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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,530	03/12/2001	Preeti Lal	PF-0551 USN	2356
27904	7590	03/18/2004	EXAMINER	
INCYTE CORPORATION 3160 PORTER DRIVE PALO ALTO, CA 94304			HINES, JANA A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,530

Applicant(s)

LAL ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 9, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 22-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Amendment Entry

1. The amendment filed December 9, 2003 has been entered. Claims 1-21 have been cancelled. Claims 22-41 have been entered. Claims 22-41 are under consideration.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 22-23 and 30-31 are drawn to an isolated polypeptide selected from the group of polypeptides consisting of SEQ ID NO: 1-6, identical amino acid sequences, biologically active fragments and immunogenic fragments and a method of producing the polypeptide.

Group II, claim(s) 24-29 and 33-34 are drawn to an isolated polynucleotide selected from the group consisting of SEQ ID NO: 7-12, naturally occurring polynucleotide sequences, complementary polynucleotides, and RNA equivalents.

Group III, claim(s) 32 is drawn to a purified antibody.

Group IV, claim(s) 35-36 are drawn to a method of detecting target polynucleotides comprising hybridization techniques.

Group V, claim(s) 37 is drawn to a method of detecting target polynucleotides comprising amplification techniques.

Group VI, claim(s) 38-41 are drawn to a microarray and a method of generating an expression profile.

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3. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups II and I are drawn to a plurality of disclosed patentably distinct inventions (polypeptides and polynucleotides comprising materially different amino acid or nucleotide sequences as evidenced by separate SEQ ID Numbers). The separate polypeptides and polynucleotides bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers. Therefore, each disclosed patentably distinct polypeptide and polynucleotide is considered a separate invention. It is noted that the sequences are not restricted by a species election, rather the sequences are individually distinct and each sequence represents an invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing which inventions are obvious variants of each other or clearly admit on the record which inventions are obvious variants of each other. If the inventions are deemed obvious variants of each other, then if the examiner finds one of the inventions unpatentable over the prior art, the evidence submitted by applicant or admission of record by applicant may be used in a rejection under 35 U.S.C. §103(a) of the other inventions. Therefore, applicants' comments about the Markush groupings are moot.

Inventions drawn to the isolated polypeptides, polynucleotides and antibodies, as seen in groups I-III, are related as different products. The products are distinct as claimed because they have different structures and different uses. Each group has a different function, effect and is capable of use without the other. For instance, the

polynucleotide products can encode while the antibody product cannot. Each group has a different structure, produces different effects and has different functions when compared to the other group. Moreover, the products of groups I-III have a different technical feature when compared to the method of detection, which recites steps for finding hybridizing polynucleotides. Therefore, the products and methods of the inventions are distinct as claimed and have separate special technical features.

Inventions IV-VI are related as methods. The methods are distinct as claimed because they have different methods with different method steps; different functions and the effects have different final outcomes. Group IV is drawn to a hybridization method, while group VI is drawn to a method of generating an expression profile. The method of Group VI has a different function, generating an expression profile, which is entirely different from either method of detection using hybridization or amplification procedures. The methods of group IV-VI do not produce the same results. Each group produces different effects and different functions when compared to the other group. Therefore, the inventions are unrelated.

Applicants' selection of claims 22-31 is moot, because the claims have not been grouped in that manner. Therefore applicants' should elect a group of claims and the corresponding sequences in accordance with the groups recited above.

Applicants' argument that the groups are not distinct is not found persuasive because contrary to applicants arguments the inventions have been shown to be distinct in view of: different structures as evidenced by the different sequence numbers;

the production of different effects as evidenced by the different methods; and the capability of the different functions as compared to the other groups as recited above. Thus, the separate and distinct use with different effects and function; therefore it is patentably distinct. Moreover, each group has been shown to be distinct, thus the restriction is maintained.

Applicants argue that there would be no serious burden on the Examiner to search for the other groups. However, because the inventions are distinct for the reasons given above and the search required for Group I is not required for any other Groups, restriction for examination purposes as indicated is proper. Searching for the polypeptide does not require, for example, to also search for antibody binding, method of detecting the polynucleotides and for microarrays. Therefore applicants' argument that the search is not burdensome is not persuasive.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines *ap*
March 8, 2004

L. F. Smith
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER (USPTO)